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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,883	ROVINSKI ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *9-12 and 18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/12/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/20/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending in the present application.

Applicant's election without traverse of Group I (Claims 1-8 and 13-17), drawn to a method for generating in a host a virus neutralizing level of antibodies to a primary HIV isolate using a DNA molecule encoding an envelope glycoprotein of a primary isolate of HIV-1 and an attenuated viral vector expressing at least an envelope glycoprotein of a primary isolate of HIV-1, in the reply filed on 10/29/04 is acknowledged.

Claims 9-12 and 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/29/04.

Accordingly, claims 1-8 and 13-17 are examined on the merits herein.

Information Disclosure Statement

The information disclosure statement filed 2/20/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein in which there is no provided copy of the publication has not been considered.

Specification

The disclosure is objected to because in the section of Brief Description of the Drawings, Figures 11 and 12 are referred to. However, only Figures 11A-B and Figures 12A-U are present in the specification.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because it contains a non-elected embodiment (a boosting antigen is a non-infectious, non-replicating, immunogenic HIV-like particle having at least the envelope glycoprotein of a primary isolate of HIV-1). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

With respect to the elected invention, the instant claims are drawn to a method for generating in a host a virus neutralizing level of antibodies to a primary HIV isolate, comprising: at least one administration of a priming antigen to the host, wherein the priming antigen comprises a DNA molecule encoding an envelope glycoprotein of a primary isolate of HIV-1, resting the host for at least one specific resting period to provide for clonal expansion of an HIV antigen specific population of precursor B-cells therein to provide a primed host, and at least one administration of a boosting antigen to the primed host to provide the neutralizing level of antibodies, wherein the boosting antigen is an attenuated viral vector expressing at least an envelope glycoprotein of a primary isolate of HIV-1; the same method with various limitations recited in the dependent claims.

With respect to the elected invention, the specification teaches by exemplification showing the construction of a plasmid pCMV3BX08 containing a sequence encoding an envelope glycoprotein from the clade B HIV-1 primary isolate Bx08 (example 1) and the production of a recombinant pox virus vCP1579 containing the HIV-1 *gag* and protease genes obtained from the HIV-1 IIIB isolate, the encoding gp120 envelope sequences

obtained from the HIV-1 Bx08 primary isolate, and sequences encoding a polypeptide containing known human CTL epitopes from HIV-1 *Nef* and *Pol* (example 4). Applicants further disclosed that primary immunizations (pCMV3Bx08) were given on weeks 0 and 4 with boosts on weeks 24 and 44 [(ALVAC(2) Bx08 or vCP1579] to macaques (example 5, Groups 3-4 and 6 in Tables 1-2). Low levels of anti-*env* antibody were detected, however high levels of anti-*gag* antibodies were obtained in Groups 3-4 with no HIV-1 specific antibodies were detected in the control Group 6 (Figures 6-7). Applicants further demonstrated that the antibodies raised in the immunized macaques are capable of neutralize HIV-1Bx08 virus in human PBMC in a neutralization assay based on the reduction of p24 levels (Table 2).

When read in light of the specification, the sole purpose for a method for generating in a host a virus neutralizing level of antibodies to a primary HIV isolate as claimed is to attain prophylactic effects against HIV infection in a human host (see paragraphs [0001], [0007], [0008], "Immunizing against HIV infection" as the title of the invention). There is no other disclosed uses for the generation of a virus neutralizing level of antibodies to a primary HIV isolate in other non-human hosts in the present application. Particularly, human is the only known natural host for HIV which causes AIDS in the human host. As enablement requires the specification to teach how to make and **use** the claimed invention, the instant specification is not enabled for the use of the method as claimed for the reasons set forth below.

1. The breadth of the claims

With respect to the elected invention, the broad claims encompass a method for generating in any host, particularly a human host as contemplated by Applicants (see page 2 of the specification, line 22), a virus neutralizing level of antibodies to any primary HIV isolate (not necessarily limited to primary HIV-1 isolates), comprising: at least one administration of any priming antigen to the host, as long as the priming antigen comprises a DNA molecule encoding an envelope glycoprotein of a primary isolate of HIV-1, resting the host for at least one specific resting period to provide for clonal expansion of an HIV antigen specific population of precursor B-cells therein to provide a primed host, and at least one administration of a boosting antigen to the primed host to provide the neutralizing level of antibodies, wherein the boosting antigen is any attenuated viral vector expressing at least an envelope glycoprotein of a primary isolate of HIV-1 (the expressed envelope glycoprotein in the boosting antigen may or may not be the same as the envelope glycoprotein in the priming antigen).

2. The state and unpredictability of the prior art

At about the effective filing date of the present application (04/27/2000), the existence of an effective HIV vaccine was and continues to be elusive (Bojak et al., Drug Discovery Today 7:36-46, 2002; Mwau et al., J. Gene Medicine 5:3-10, 2003). There are several major scientific obstacles blocking the development of a successful preventive HIV vaccine. These include (1) the extraordinary variability of HIV strains which occur in different parts of the world over time and in patients, (2) the lack of an exact animal model of HIV-induced AIDS, and (3) the lack of understanding of correlates of positive immunity to HIV. Even in 2004, Desrosiers, R.C. (Nature Medicine

10:221-223, 2004) still state "Several lines of evidence indicate that development of an effective vaccine for HIV-1 is going to be, at best, extremely difficult. The inability to solve fundamental scientific questions is the root cause for why a successful vaccine is not currently within our grasp." (abstract). Pantaleo et al. (Nature Medicine 10:806-810, 2004) also state "The lack of understanding of some crucial scientific questions (such as how to generate neutralizing antibodies), the fact that current HIV vaccine candidates may not protect from infection, and the absence of definitive experimental evidence that certain types of immune responses are indeed immune correlates of protection all favor the view that more basic research is needed before current vaccine candidates can be moved into large efficacy trials. However, it is also unclear what data from which animal model of HIV-1 infection are most relevant to human infection and vaccine protection." (page 809, col. 2, section entitled "Final considerations"). Therefore, it is apparent that the attainment of prophylactic effects against HIV infection in a human host remains elusive and unpredictable in 2004, let alone at the effective filing date of the presently claimed invention (4/27/2000).

The unpredictability of the relevant art is also supported by the teachings of Richmond et al. (Virology 230:265-274, 1997) and Caver et al. (Vaccine 17:1567-1572, 1999, IDS). Richmond et al. highlighted the low immunogenic potential of the HIV-1 Env and that different Envs have different potentials to raise low titer neutralizing antibody, and none of the Envs raised significant titers of neutralizing antibody for the patient isolates (see abstract). Caver et al. reported that a strong antibody response to a T cell line adapted virus IIIB gp120 did not predict a response to heterologous Chiang

Mai gp120 (see Figure 4). Caver et al. also stated "The variability in the quality of antibody responses among mice within each group reflects the complexity of the somatic V (Variable), D (diversity) and J (joining) gene rearrangement mechanisms responsible for receptor production in developing lymphocytes. The patterns of B-cell and T-cell receptor gene rearrangement are largely stochastic and can also be influenced by gene position and environmental factors [17]. Therefore, B-cell and T-cell repertoires will differ in every animal, as will the quality of immune responses elicited by any given immunogen." (page 1571, col. 1, third paragraph), and "Lymphocyte repertoire complexities must be addressed in vaccine design strategies, as an immune response capable of neutralizing an array of diverse HIV isolates is desired in all vaccines. Conserved determinants on Env proteins that evoke cross-reactive neutralizing antibodies are rare, are often masked, and do not elicit immune responses in every individual [18]" (page 1571, col. 1, top of fourth paragraph).

3. The amount of direction or guidance provided

Apart from the exemplification showing the antibodies which were raised in macaques immunized according the prime-boost strategy set forth in Table 1 (Groups 3-4) are capable of neutralize HIV-1Bx08 virus in human PBMC in an *in vitro* neutralization assay based on the reduction of p24 levels, the instant specification fails to provide sufficient guidance for a skilled artisan on how to attain any prophylactic effects against any primary HIV isolate in a human host as contemplated by Applicants. The results obtained in example 5 are not reasonable correlated to any prophylactic effects in a human host that are contemplated by Applicants. This is because of several

lines of evidence already set forth by Desrosiers, R.C. (Nature Medicine 10:221-223, 2004). They include: (1) the natural immune response is not effective because individuals infected with HIV-1 mount apparently strong antibody responses and viral-specific CD8+ cellular responses, and yet HIV-1 continues to replicate and eventually kills the hosts; (2) the failure to protect monkeys against cloned, homogenous against SIV239 even under ideal experimental conditions; (3) the failure of controlled HIV-1 infection to protect against pathogenic superinfection; (4) the enormous sequence heterogeneity among individual isolates of HIV-1; (5) the failure of the phase III VaxGen trial. Therefore, it is uncertain whether the level of neutralizing antibodies elicited in macaques in example 5 is effective to yield any prophylactic effect in a human host against any HIV-1 primary isolate, let alone for any primary HIV isolate. Interestingly, it is also noted that only low levels of **anti-*env* antibody** were detected in sera of macaques treated by the immunization regimes of the present application (see Fig. 6A-B and Fig. 7). In 2004, Desrosiers, R.C. still state "First, we do not know how to elicit antibodies with potent neutralizing activity. Second, we do not know how to deal with the enormous sequence variability of the virus. Third, ...we do not understand the crucial components of the protective immune response...Finally, we do not know whether immunologic memory will ever be sufficient to protect against HIV-1. If it will not be sufficient, we need to learn how to elicit protective immune responses in a way that will persist." (page 222, col. 3, first paragraph). Additionally, Pantaleo et al. (Nature Medicine 10:806-810, 2004) note that even in 2004 a skilled artisan still does not know how to induce high titers of neutralizing antibodies, and whether any of the vaccines

being developed would elicit cellular immune responses that will correlate with protection from infection or disease progression (see Box 1 on page 809). Therefore, in light of the totality of the prior art on HIV vaccine at the effective filing date of the present application as discussed above, coupled with the lack of sufficient guidance provided by the present disclosure, it would have required undue experimentation for a skilled artisan to **use** the claimed method to attain any prophylactic effects against any primary HIV isolate as contemplated by Applicants.

With respect to the broad claims (claims 1, 6-8 and 13-17) encompassing the administration into a host any priming antigen, as long as the priming antigen comprises a DNA molecule encoding an envelope glycoprotein of a primary isolate of HIV-1, including an attenuated viral vector comprising the same DNA molecule (and an attenuated viral vector would also be used to deliver a boosting antigen), the instant specification fails to provide sufficient guidance for a skilled artisan on how to attain a neutralizing level of antibodies to a primary HIV isolate under such a situation, let alone an effective virus neutralizing level of antibodies to a primary HIV isolate in a host to yield the prophylactic effect contemplated by Applicants. It is noted the specification teaches specifically the failure to attain any neutralizing antibody when BX08 DNA was used both as a primed and a boosting antigen (see Group 5 in Tables 1 and 2). Moreover, a weak immune response has been elicited by recombinant plasmid DNA vectors when they are used singly in an "HIV-related" study (Lu et al., Vaccine 15:920-923, 1997), and that strong immune responses against viral vectors have been known to be induced and effectively block the efficacy of booster immunizations (e.g.,

suppression the efficacy and duration of the B-cell response to the recombinant gene product) using the same viral vectors, particularly for recombinant vaccinia virus vectors (Kundig et al, Vaccine 11:1154-1158, 1993). Thus, given the lack of sufficient guidance provided by the present disclosure coupled with the state of the prior art at the effective filing date of the present application, it would have required undue experimentation for a skilled artisan to make and use the method as claimed to attain any prophylactic effects against any primary HIV isolate contemplated by Applicants.

Additionally, with respect to the broad claims encompassing the situation in which both the priming and boosting antigen do not necessarily contain a sequence encoding for the same envelope glycoprotein of a primary isolate of HIV-1, neither the instant disclosure nor the prior art at the effective filing date of the present application provide any evidence indicating or suggesting that any "booster effect" with respect to a virus neutralizing level of antibodies to a primary HIV isolate could be attained in such a situation, let alone for one that yields a prophylactic effect contemplated by Applicants. Once again, with the lack of sufficient guidance provided by the instant specification and in light of the totality of the prior art as discussed above it would have required undue experimentation for a skilled artisan to make and use the method as claimed to attain any prophylactic effects against any primary HIV isolate contemplated by Applicants.

With respect to claims 5 and 16 that specifically recite the administration of the vector that has the identifying characteristics of pCMV3Bx08 (including the pCMV3Bx08 vector) and the attenuated canary pox virus vector that has the identifying characteristics of vCP1579 (including the vCP1579 vector), respectively; and therefore

they are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that the biological materials, particularly the vectors pCMV3Bx08 and vCP1579, are essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809. Since it is unclear whether the vector that has the identifying characteristics of pCMV3Bx08 and the attenuated canary pox-virus vector that has the identifying characteristics of vCP1579 are known and readily available to the public or that the written instructions are sufficient to reproducibly construct these biological materials from starting materials known and readily available to the public. Accordingly, availability of such biological materials is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be

verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

4. Working example provided

There is an absence of an example demonstrating that a prophylactic effect against any primary HIV isolate could be attained in a human host as contemplated by Applicants.

Accordingly, due to the lack of guidance provided by the specification regarding to the issues set forth above, the breadth of the claims, and the unpredictability of the relevant art on HIV vaccine, it would have required undue experimentation for one skilled in the art to make and **use** the instantly claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said neutralizing levels of antibodies" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because prior to this limitation, the claim recites "a virus neutralizing level of antibodies" in the preamble of the claim. This renders the claim and its dependent claims indefinite

because the metes and bounds of the claims are not clearly determined. What other neutralizing levels of antibodies does claim 1 appear to refer to? Clarification is requested.

In claim 5, it is unclear what is encompassed by the phrase "the vector has the identifying characteristics of pCMV3Bx08 shown in Figure 2". It is uncertain which identifying characteristics of pCMV3Bx08 shown in Figure 2 that the vector utilized in the claimed method should or should not have for generating in a host a virus neutralizing level of antibodies to a primary HIV isolate. Clarification is requested because the metes and bounds of the claim are not clearly determined.

Similarly in claim 16, it is unclear what is encompassed by the phrase "the attenuated canary poxvirus vector has the identifying characteristics of vCP1579". Once again, it is uncertain which identifying characteristics of vCP1579 the attenuated viral vector utilized in the claimed method should or should not have for generating in a host a virus neutralizing level of antibodies to a primary HIV isolate. Clarification is requested because the metes and bounds of the claim are not clearly determined.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8 and 13-17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 and 13-17 of copending Application No. 10/257,962. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Caver et al (Vaccine 17:1567-1572, March 1999; IDS) disclose a method in which C57BL/6 female mice were injected with a plasmid DNA containing a sequence encoding a 640 amino acid III-B derived gp140 Env (BH10) operably linked to a CMV enhancer/promoter at week 0, followed by a recombinant vaccinia virus vector expressing the same 640 amino acid IIIB-derived BH10 protein at week 8 and a purified protein comprising a mixture of a IIIB-related gp120 and IIIB-derived gp41 at week 16 (see Fig. 1, group 11). It was shown these immunized mice exhibited a strong neutralizing activity against HIV IIIB in a neutralizing assay, in that their sera were able to reduce a dose of approximately 1000 $TCID_{50}$ (IIIB virus) by more than 2.5 logs of infectivity (page 1569, col. 2, middle paragraph; Figure 3).

However, HIV-IIIB is a T cell line adapted virus, which is not typical of a primary HIV isolate, as evidenced by the teachings of Richmond et al. (Virology 230:265-274, 1997; see abstract, page 265, col. 1 and page 269, col. 1, first sentence of the second

paragraph). Additionally, it is also unclear whether the recombinant vaccinia virus utilized by Caver et al. is attenuated.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Quang Nguyen, Ph.D.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.